EXHIBIT 17

EUROPEAN UROLOGY 58 (2010) 218–238

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

European Association of Urology

Platinum Priority – Female Urology – Incontinence

Editorial by Firouz Daneshgari on pp. 239–241 of this issue

Updated Systematic Review and Meta-Analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence

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Article info

Article history:
Accepted April 13, 2010
Published online ahead of print on April 23, 2010

Keywords:
Stress urinary incontinence
Burch colposuspension
Pubovaginal sling
Stress urinary incontinence
Retropubic vaginal tape
Tension-free tape
Transobturator tape

Abstract

Context: Burch colposuspension, pubovaginal sling, and midurethral retropubic tape (RT) and transobturator tape (TOT) have been the most popular surgical treatments for female stress urinary incontinence (SUI). Several randomized controlled trials (RCTs) have been published comparing the different techniques, with conflicting results.

Objective: Our aim was to evaluate the efficacy, complication, and reoperation rates of midurethral tapes compared with other surgical treatments for female SUI.

Evidence acquisition: A systematic review of the literature was performed using the Medline, Embase, Scopus, Web of Science databases, and Cochrane Database of Systematic Reviews.

Evidence synthesis: Thirty-nine RCTs were identified. Patients receiving midurethral tapes had significantly higher overall (odds ratio [OR]: 0.61; confidence interval [CI]: 0.46–0.82; $p = 0.00009$) and objective (OR: 0.38; CI: 0.25–0.57; $p < 0.0001$) cure rates than those receiving Burch colposuspension, although they had a higher risk of bladder perforations (OR: 4.94; CI: 2.09–11.68; $p = 0.00003$). Patients undergoing midurethral tapes and pubovaginal slings had similar cure rates, although the latter were slightly more likely to experience storage lower urinary tract symptoms (LUTS) (OR: 0.31; CI: 0.10–0.94; $p = 0.04$) and had a higher reoperation rate (OR: 0.31; CI: 0.12–0.82; $p = 0.02$). Patients treated with RT had

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0302-2838/$ – see back matter doi:10.1016/j.eururo.2010.04.022

slightly higher objective cure rates (OR: 0.8;CI: 0.65–0.99; $p = 0.04$) than those treated with TOT; however, subjective cure rates were similar, and patients treated with TOT had a much lower risk of bladder and vaginal perforations (OR: 2.5; CI: 1.75–3.57; $p < 0.00001$), hematoma (OR: 2.62; CI: 1.35–5.08; $p = 0.005$), and storage LUTS (OR: 1.35; CI: 1.05–1.72; $p = 0.02$). Meta-analysis demonstrated similar outcomes for TVT-O (University of Liège, Liège, Wallonia, Belgium) and Monarc (AMS, Minnetonka, MN, USA).

Conclusions: Patients treated with RT experienced slightly higher continence rates than those treated with Burch colposuspension, but they faced a much higher risk of intraoperative complications. RT and pubovaginal slings were similarly effective, although patients with pubovaginal slings were more likely to experience storage LUTS. The use of RT was followed by objective cure rates slightly higher than TOT, but subjective cure rates were similar. TOT had a lower risk of bladder and vaginal perforations and storage LUTS than RT. The strength of these findings is limited by the heterogeneity of the outcome measures and the short length of follow-up.

1. Introduction

Female stress urinary incontinence (SUI) is a common condition, with prevalence rates ranging from 12.8% to 46.0% [1]. Although several methodological issues can influence the epidemiological figures, there is no question that female SUI has an significant negative impact on quality of life and, in particular, on the social, physical, psychological, occupational, and sexual aspects of life [2]. Moreover, management of SUI puts an enormous burden on the health care system, estimated to be as high as $19.5 billion annually in the United States [3] and £740 million annually in the United Kingdom [4].

Surgical treatment is the standard approach for women with SUI who have failed conservative management strategies such as lifestyle changes, physical therapies, scheduled voiding regimes, and behavioral therapies [5]. Although hundreds of different surgical procedures have been reported, the ideal surgical technique—that is, a procedure that is simple, inexpensive, easy to learn and perform, minimally invasive, with high and durable efficacy, and without long-term morbidity and functional sequelae—does not yet exist [6].

Both Burch colposuspension and pubovaginal slings are time-honored procedures, with solid evidence of their efficacy at long-term follow-up. Specifically, both procedures have been reported to be followed by 10-yr success rates in the range of 55–70% [7]. However, neither of the techniques is minimally invasive, and both are followed by significant risks of de novo storage symptoms (8–27% following colposuspension and 3–23% following pubovaginal sling), voiding dysfunction (2–27% following colposuspension and up to 11% with 1.5–7.8% long-term self-catheterization following pubovaginal sling), and pelvic organ prolapse (2.5–27% following colposuspension) [7].

Since the first reports from the Ulmsten group [8], the application of tension-free vaginal tape (TVT), the first polypropylene midurethral tape put on the market, has become one of the most commonly performed procedures worldwide, largely because of the ease of performing the procedure and its short-term high success rates. In 2008, Nilsson et al reported outcomes 11 yr after the operation, demonstrating that 90% of the women treated were still objectively cured at the last follow-up without any significant late-onset adverse effects [9].

Since the advent of TVT, other retropubic tapes (RT) and, more recently, transobturator tapes (TOT) have been introduced, making midurethral sling procedures both less invasive and safer [10].

Based on a systematic literature search performed in January 2007, Novara et al reported two systematic reviews and meta-analyses of randomized controlled trials (RCTs) evaluating the efficacy and complication rates of TVT compared with Burch colposuspension, pubovaginal slings, and other midurethral tapes [11,12]. On the whole, the data from the two meta-analyses suggested that TVT was significantly more effective than colposuspension and was followed by similar complication rates; the data also showed that TVT was similar in efficacy to pubovaginal slings, which are followed by significantly higher perioperative morbidity. Finally, the two meta-analyses demonstrated that TVT and TOT had similar efficacy, although the risk of bladder perforations, pelvic hematoma, and storage lower urinary tract symptoms (LUTS) was significantly less common in patients treated with TOT [11,12].

The strength of the recommendations derived from these two meta-analyses was limited by the short median follow-up and poor methodological quality of several of the RCTs included. Since then, several other RCTs have been published, mainly comparing RT with TOT and featuring longer follow-up extensions than some of the other previously available studies [13,14]. Consequently, based on the recommendation of the Cochrane Collaboration to update systematic reviews at least every 2 yr [15], we elected to update our previous meta-analyses of the literature in the field of midurethral slings for the treatment of primary female SUI.

2. Evidence acquisition

2.1. Materials and methods

The updated systematic review of the literature was performed in August 2009 using the Medline, Scopus, Web of Science, and Embase databases. The Medline search used a complex search strategy including both medical subject heading (MeSH) and free-text protocols, as was done in the previous review [11,12]. Specifically, the MeSH search was conducted by combining the following terms retrieved from the MeSH browser provided by Medline: *Urinary Incontinence, Stress,* and *Suburethral Slings.* Multiple free-text searches were also performed, searching for the following terms individually in the fields title and abstract of the records: *Urinar*incont*, TVT, tension-free vaginal tape*, Tension-free vaginal sling*, Transobturator tape*, Transobturator sling*, TVT-obturator, TVT-O, TOT, suprapubic arc sling*, SPARC sling*, intravaginal slingplasty, IVS sling, Uratape, ObTAPE, Prepubic sling*, Prepubic TVT, Prepubic tape*, PelviLace, Ureter, Aris, In-Fast, Monarc, I-Stop,* and *BioArc.* Subsequently, the search results were pooled, and the following limits used: humans, Entrez date from January 1, 2007. No limitations regarding language of publication or type of publication were used. The searches on Embase, Scopus, and Web of Science used only the free-text protocol, with the same keywords. Subsequently, the query results were pooled and the same temporal limit applied. Moreover, Cochrane Database of Systematic Reviews was searched using the keyword *urinary incontinence.* A manual search of congress abstracts was not performed.

A total of 327 records were retrieved from Medline, 601 from Scopus, 502 from Embase, and 405 from Web of Science. Three of the authors reviewed the full texts to select the papers relevant to the review topic. Discrepancies were solved by open discussion. Specifically, all the RCTs discussing outcomes (ie, continence rates, satisfaction rates, complication rates) from the use of midurethral slings were selected. A single Cochrane review of the pertinent topic was identified [16]. The reference list was searched, identifying 14 further trials.

The selected papers were categorized according to the grade of evidence: An adequately sampled single RCT was considered to have level 1b evidence, a low-quality RCT to have level 2b evidence [17].

The quality of the retrieved RCTs was assessed using the Jadad score [18]. A numerical score between 0 and 5 was assigned as a rough measure of study design and reporting quality, with 0 the weakest and 5 the strongest. One point was assigned if the trial was either randomized or double blinded, and one point was given if an accurate description of dropout patients was provided. Further points were given if randomization and blinding procedures were appropriate; points were subtracted if randomization and blinding procedures were inappropriate or inadequately described. An overall score $\geq$3 indicated a high-quality study [18].

To evaluate the efficacy of the different procedures, both objective criteria (stress test, pad test) and subjective

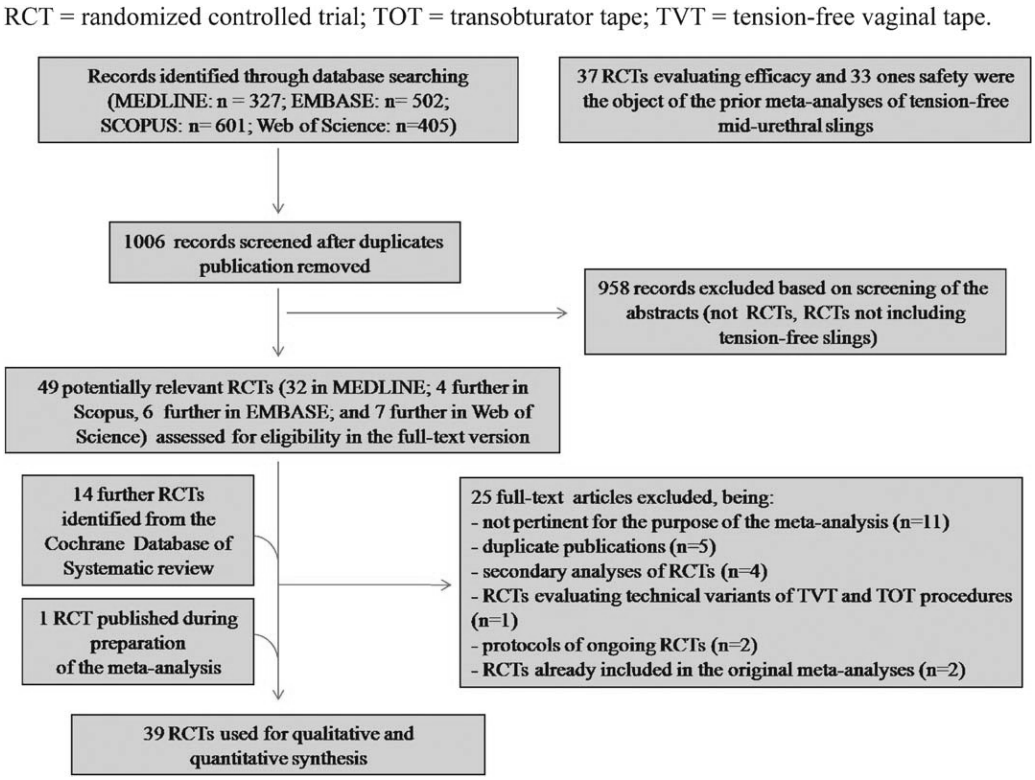


Fig. 1 – Flow diagram of the systematic review and meta-analysis.
RCT = randomized controlled trial; TOT = transobturator tape; TVT = tension-free vaginal tape.

criteria (patients' perception of the clinical improvement, expressed by validated questionnaires, institutional questionnaires, or open interview) were considered, reporting objective and subjective continence rates. In the case of papers reporting patient outcomes through the use of mixed subjective and objective end points (eg, no referred leakage and negative stress test, no referred leakage and negative pad test), an overall continence rate was shown.

Meta-analysis was conducted using Review Manager software v.4.2 (Cochrane Collaboration, Oxford, UK). Specifically, statistical heterogeneity was tested using the χ^2 test. A value of $p < 0.10$ was used to indicate heterogeneity. In the case of a lack of heterogeneity, fixed-effects models were used for the meta-analyses. The results were expressed as weighted means difference and standard deviations for continuous outcomes and as an odds ratio (OR) with a 95% confidence interval (CI) for dichotomous variables. In the comparisons of RT and TOT, the large number of publications with appropriate data allowed us to perform subgroup analysis according to the device used. For all the comparisons, sensitivity analyses limited to RCTs of good methodological quality (ie, those with a Jadad score ≥ 3) were performed. The presence of publication bias was evaluated through a funnel plot, as previously reported [19]. Briefly, a funnel plot is a scatter plot of the treatment effect estimated by individual studies versus a measure of study size or precision. In this graphic representation, larger and more precise studies are plotted at the top, near the combined effect size, and smaller and less precise studies show a wider distribution below. If there were no publication bias, the studies would be expected to be symmetrically distributed on both sides of the combined effect size line. In the case of publication bias, the funnel plot may be asymmetric because the absence of studies would distort the distribution on the scatter plot.

The study complied with the recently reported Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement [20].

3. Evidence summary

Fig. 1 summarizes the literature review process that led to the identification of the 39 RCTs used to update the meta-analysis. Specifically, 7 RCT compared TVT [21–27] and a single TOT [28] with Burch colposuspension; 4 compared RT [29–32] and 1 TOT [33] with autologous pubovaginal slings; 23 compared RT with TOT [34–56], and finally, 3 RCTs compared different TOT [57–59]. Among these publications, there were 14 congress abstracts [21–25,29,31,33,34,36, 38,46, 54,57]. Twelve of the 25 studies were high-quality RCTs [27,28,38,39,40,42,44,48,49,51,53,58].

3.1. *Randomized controlled trials comparing midurethral tapes to Burch colposuspension*

Sivasioglu et al compared the efficacy of Safyre-t TOT (Promedon, Cordoba, Argentina) and Burch colposuspension at 12-mo follow-up, demonstrating fairly similar cure and complication rates results for the two procedures [28].

Table 1 – Comparisons after midurethral tapes and Burch colposuspension: Meta-analysis of all of the randomized controlled trials (RCTs) and sensitivity analyses for high-quality RCTs

Midurethral tapes vs colposuspension	All RCTs						High-quality RCTs					
	RCT	Participants	OR	95% CI of OR	*p* value	Difference in favor of	RCT	Participants	OR	95% CI of OR	*p* value	Difference in favor of
						Continence rate						
Any definition of continence	11	1195	0.61	0.46–0.82	0.0009	Midurethral tape	4	628	0.48	0.34–0.69	<0.0001	Midurethral tape
Negative stress test	3	528	0.38	0.25–0.57	<0.0001	Midurethral tape	3	528	0.38	0.25–0.57	<0.0001	Midurethral tape
Negative pad test	3	310	0.86	0.49–1.51	0.61	None	2	242	0.87	0.49–1.59	0.65	None
Subjective continence rate	4	400	0.79	0.52–1.21	0.27	None	2	277	0.80	0.48–1.36	0.41	None
						Adverse events						
	RCT	Participants	OR	95% CI of OR	*p* value	Difference in favor of	RCT	Participants	OR	95% CI of OR	*p* value	Difference in favor of
Bladder perforation	6	865	4.94	2.09–11.68	0.00003	Colposuspension	3	516	5.59	2–15.63	0.001	Colposuspension
Hematoma	4	533	1.16	0.37–3.66	0.80	None	2	416	3.67	0.59–22.7	0.16	None
Urinary tract infection	7	923	1.00	0.53–1.89	0.99	None	3	572	1.92	0.69–5.32	0.21	None
Storage LUTS	10	1128	1.08	0.77–1.52	0.66	None	3	572	1.29	0.84–1.97	0.24	None
Voiding LUTS	11	1081	0.85	0.57–1.25	0.41	None	4	628	0.70	0.45–1.1	0.12	None
Reoperation rate	4	490	0.76	0.40–1.44	0.41	None	2	407	0.74	0.38–1.45	0.38	None

CI = confidence interval; LUTS = lower urinary tract symptoms; OR = odds ratio.

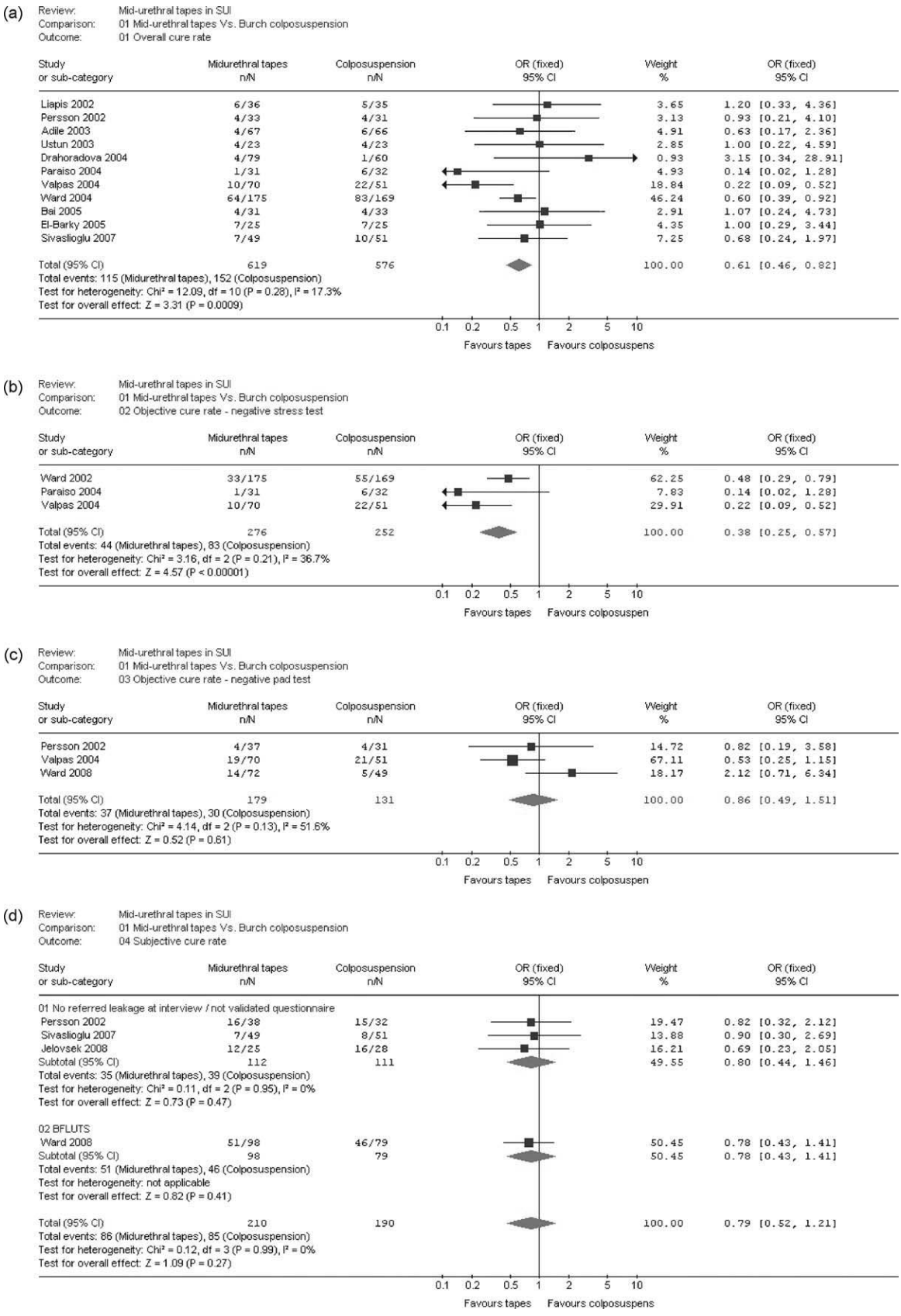
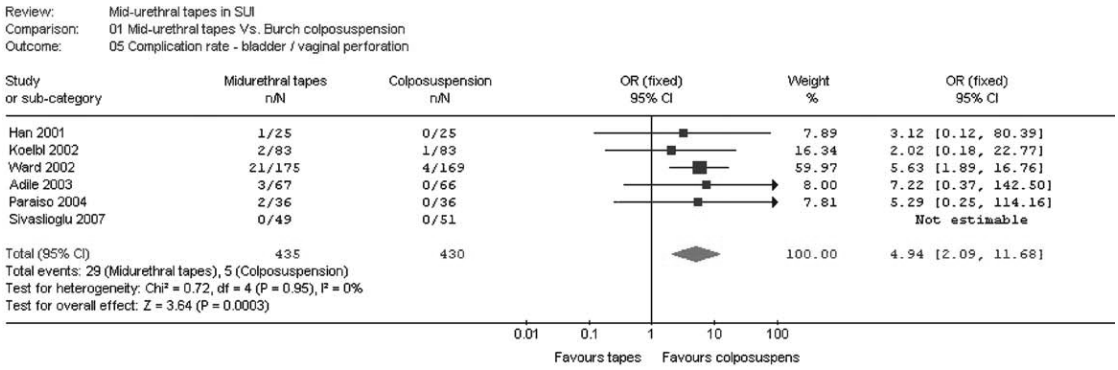


Fig. 2 – Forest plots of comparisons after midurethral tapes and Burch colposuspension. (a) Overall cure rate: continence rate according to any definition of cure; (b) continence rate according to the presence of a negative stress test; (c) continence rate according to the presence of a negative 2-h pad test; (d) subjective continence rate; (e) bladder and vaginal perforation; (f) pelvic hematoma; (g) urinary tract infection; (h) storage lower tract urinary symptoms (LUTS); (i) voiding LUTS; (j) reoperation rate.
CI = confidence interval; OR = odds ratio; SUI = stress urinary incontinence.

(e)



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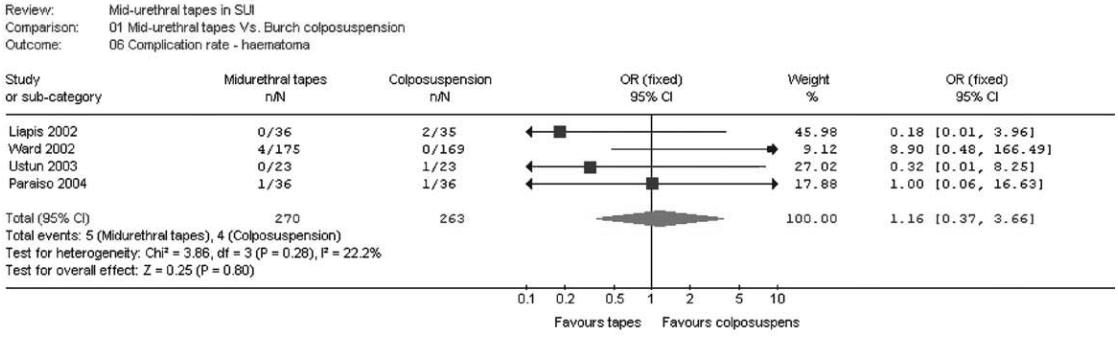
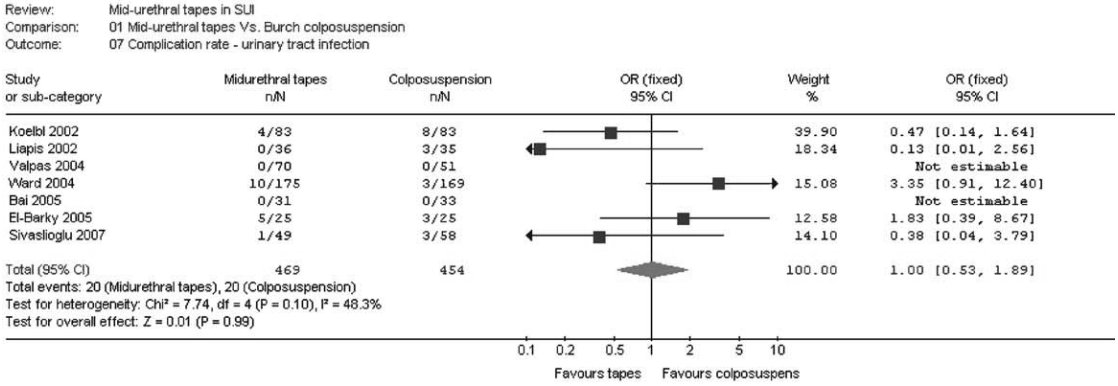


(g)



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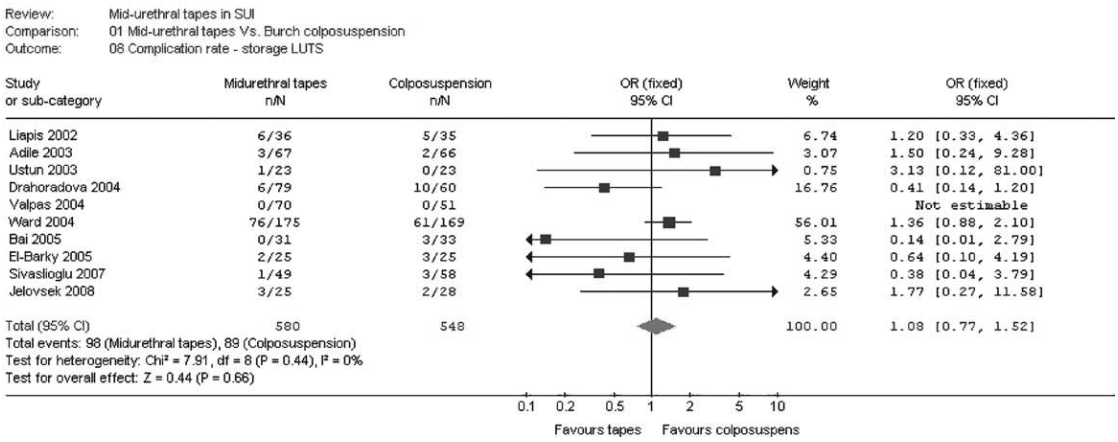


Fig. 2. (Continued)

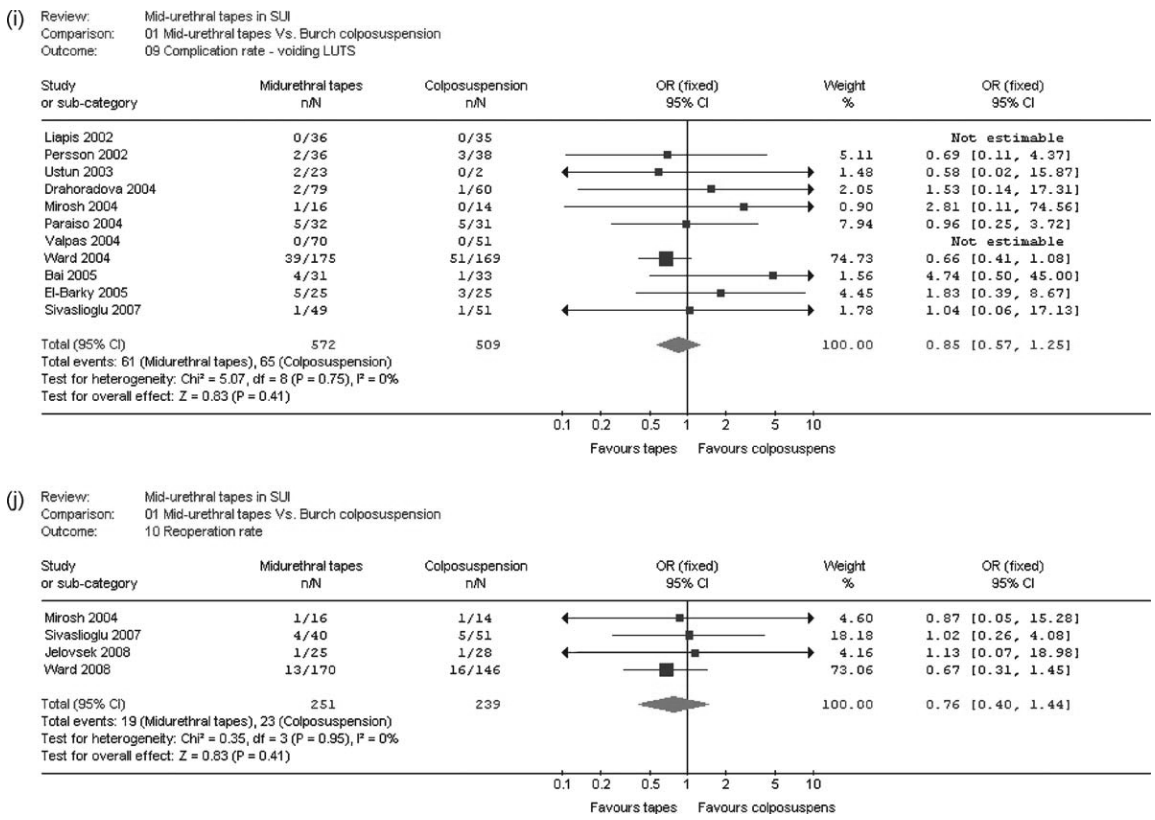


Fig. 2. (Continued).

Jelovsek et al evaluated the classical TVT in comparison with laparoscopic colposuspension at a median follow-up of 64.8 mo, reporting overlapping cure and complication rates [26]. The paper is an update of a study previously reported by Paraiso et al. [14] featuring a longer follow-up. The study from Ward et al. [27] updates at 5-yr follow-up the data from the United Kingdom and Ireland TVT Trial, a highly relevant study that previously had data available only at 2-yr follow-up [13]. All the other studies were published as congress abstracts [21–25]. Only two of these studies were of good methodological quality [27,28].

Supplemental Table 1 in the appendix summarizes continence, complication, and reoperation rates of the RCTs comparing midurethral tapes to Burch colposuspension as a treatment for primary SUI.

Fig. 2 shows the forest plots concerning the meta-analyses of cure, complication, and reoperation rates.

On the whole, midurethral tapes were followed by significantly higher cure rates than Burch colposuspension, considering success rates evaluated according to any definition of continence (OR: 0.61; 95% CI: 0.46–0.82; $p = 0.00009$; Fig. 2a) and the presence of a negative cough test (OR: 0.38; 95% CI: 0.25–0.57; $p < 0.0001$; Fig. 2b). The two procedures were similarly effective according to the presence of a negative pad test (OR: 0.86; 95% CI OR: 0.49–1.51; $p = 0.61$; Fig. 2c) and subjective continence rates (OR: 0.79; 95% CI OR: 0.52–1.21; $p = 0.27$; Fig. 2d). Sensitivity analyses limited to studies of higher methodological quality reconfirmed these identical findings (Table 1).

With regard to complication rates, bladder perforation was significantly more common after midurethral tapes (OR: 4.94; 95% CI: 2.09–11.68; $p = 0.00003$; Fig. 2e), whereas the risk of pelvic hematoma (OR: 1.16; 95% CI: 0.37–3.66; $p = 0.80$; Fig. 2f), urinary tract infections (OR: 1.35; 95% CI: 0.63–2.90; $p = 0.44$; Fig. 2g), storage LUTS (OR: 1.08; 95% CI: 0.77–1.52; $p = 0.66$; Fig. 2h), voiding LUTS (OR: 0.85; 95% CI: 0.57–1.25; $p = 0.41$; Fig. 2i), and reoperation (OR: 0.76; 95% CI: 0.40–1.44; $p = 0.41$; Fig. 2j) were similar between the two surgical treatments. Sensitivity analyses limited to studies of higher methodological quality reconfirmed these identical findings (Table 1).

3.2. *Randomized controlled trials comparing midurethral tapes to pubovaginal slings*

Basok et al compared the intravaginal sling (IVS) to cadaveric fascia lata, demonstrating similar 12-mo subjective cure rates but significantly higher rates of both persistent urgency urinary incontinence and de novo detrusor overactivity in those patients randomized to fascia lata [30]. Sharifiaghdas and Mortazavi compared the classic TVT to the autologous rectus fascia sling, demonstrating very similar outcomes at midterm follow-up [31]. Tcherniskovsky et al compared a TOT, the Safyre-t, to the autologous rectus fascia sling, reporting similar 12-mo success rates [33]. Finally, two further studies were available in the form of congress abstracts [29,31]. All five studies were of poor methodological quality.

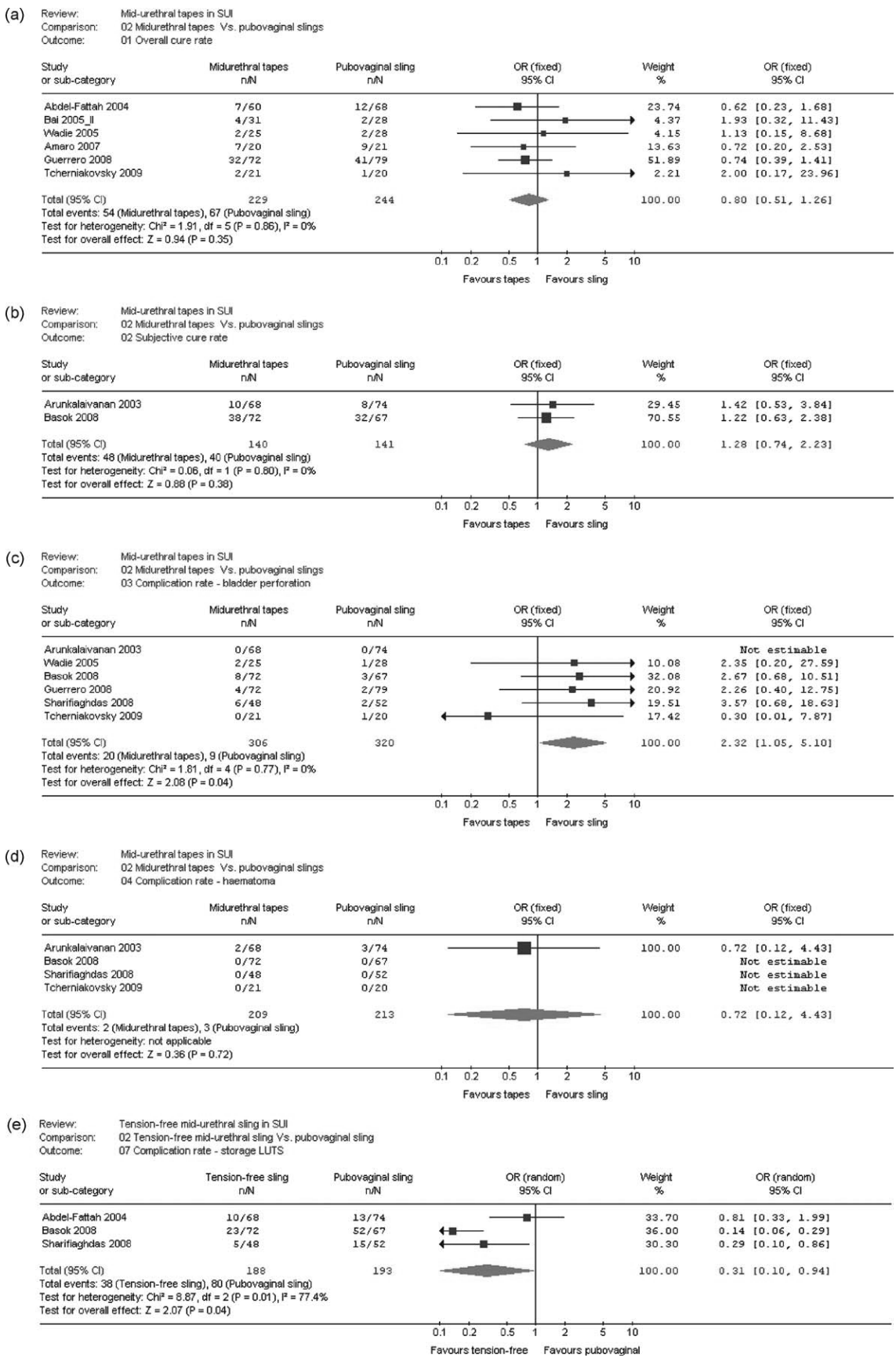


Fig. 3 – Forest plots of comparisons after midurethral tapes and pubovaginal sling: (a) Continence rate according to any definition of cure; (b) subjective continence rate; (c) bladder perforation; (d) pelvic hematoma; (e) storage lower urinary tract symptoms (LUTS); (f) voiding LUTS; (g) reoperation rate. CI = confidence interval; OR = odds ratio; SUI = stress urinary incontinence.

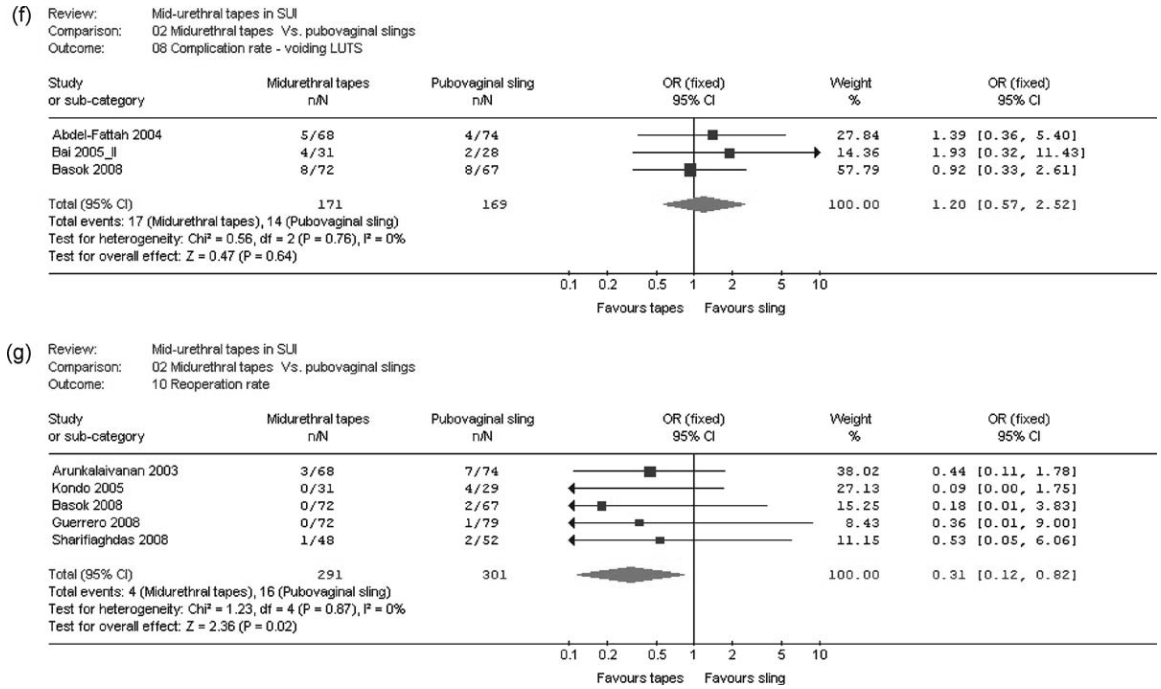


Fig. 3. (Continued).

Supplemental Table 2 in the appendix summarizes continence, complication, and reoperation rates of the RCTs comparing midurethral tapes with pubovaginal slings as the treatment for primary SUI.

Fig. 3 shows the forest plots concerning the meta-analyses of continence, complication, and reoperation rates.

Midurethral tapes and pubovaginal slings had similar efficacy in terms of both overall (OR: 0.80; 95% CI OR: 0.51–1.26; $p = 0.35$; Fig. 3a) and subjective continence rate (OR: 1.28; 95% CI OR: 0.74–2.23; $p = 0.38$; Fig. 3b).

With regard to complication, the risk of intraoperative bladder perforation (OR: 2.32; 95% CI OR: 1.05–5.10; $p = 0.04$; Fig. 3c) were significantly lower in the sling group; pelvic hematoma (OR: 0.72; 95% CI OR: 0.12–4.43; $p = 0.72$; Fig. 3d) was similar in the two procedures. However, midurethral tapes were followed by significantly lower risk of storage LUTS (OR: 0.31; 95% CI OR: 0.10–0.94; $p = 0.04$; Fig. 3e) and reoperation (OR: 0.31; 95% CI OR: 0.12–0.82; $p = 0.02$; Fig. 3g). The prevalence of voiding LUTS (OR: 1.20; 95% CI OR: 0.57–2.52; $p = 0.64$; Fig. 3f) was also similar in the two procedures.

The only RCT of good methodological quality [60] demonstrated similar subjective cure and complication rates between the two surgical techniques.

3.3. *Randomized controlled trials comparing retropubic with transobturator tape*

Specifically, 11 RCTs compared classic TVT with inside-out TOT (TVT-O in 10 [38,39,41–43,47, 48,50,51,55,56] and less invasive free tape in a single one [36]; 9 compared TVT to outside-in TOT (Obtape in two studies [37,40], Monarc in 4 [44–46,49], Iris-TOT in a single one [34], and Obtrix in a single one [53], whereas the implanted devices were not specified in a single study [55]); a single one compared TVT to both TVT-O and Monarc [54]; a single one compared retropubic IVS to outside-in IVS [52], and a single one compared retropubic suprapubic arc (SPARC) sling to Monarc [35].

Supplemental Tables 3 and 4 in the appendix summarize continence, complication, and reoperation rates of the RCTs comparing RT and TOT as the treatment for primary SUI.

Fig. 4 shows the forest plots concerning the meta-analyses of continence, complication, and reoperation rates.

On the whole, overall (OR: 1.02; 95% CI OR: 0.78–1.33; $p = 0.90$; Fig. 4a), and subjective (OR: 0.97; 95% CI OR: 0.75–1.24; $p = 0.80$; Fig. 4c) continence rates were overlapping in the two procedures. Interestingly, among the studies providing subjective outcomes using validated questionnaires, postoperative Urogenital Distress Inventory (UDI-6) (WMD: 0.07; 95% CI: −0.39–0.53; $p = 0.76$; Fig. 4d) and Incontinence Impact Questionnaire (IIQ-7) (WMD: 0.01; 95% CI: −0.22–0.24; $p = 0.95$) scores were similar. Notably, RT were followed by significantly higher objective continence rates (OR: 0.80; 95% CI OR: 0.65–0.99; $p = 0.04$; Fig. 4b). Moreover, a statistically significant difference in favor of TVT was shown when comparing objective continence rates between TVT and inside-out TOT (OR: 0.71; 95% CI OR: 0.52–0.96; $p = 0.03$; Fig. 4b), whereas no difference was found comparing TVT to outside-in TOT (OR: 0.90; 95% CI OR: 0.66–1.22; $p = 0.51$; Fig. 4b). Sensitivity analyses limited to studies of higher methodological quality showed only a nonstatistically significant trend in favor of TVT with regard to objective cure rate (OR: 0.74; 95% CI OR: 0.54–1.01; $p = 0.05$). No differences in subjective and overall continence rates were found in the other sensitivity analyses (Table 2).

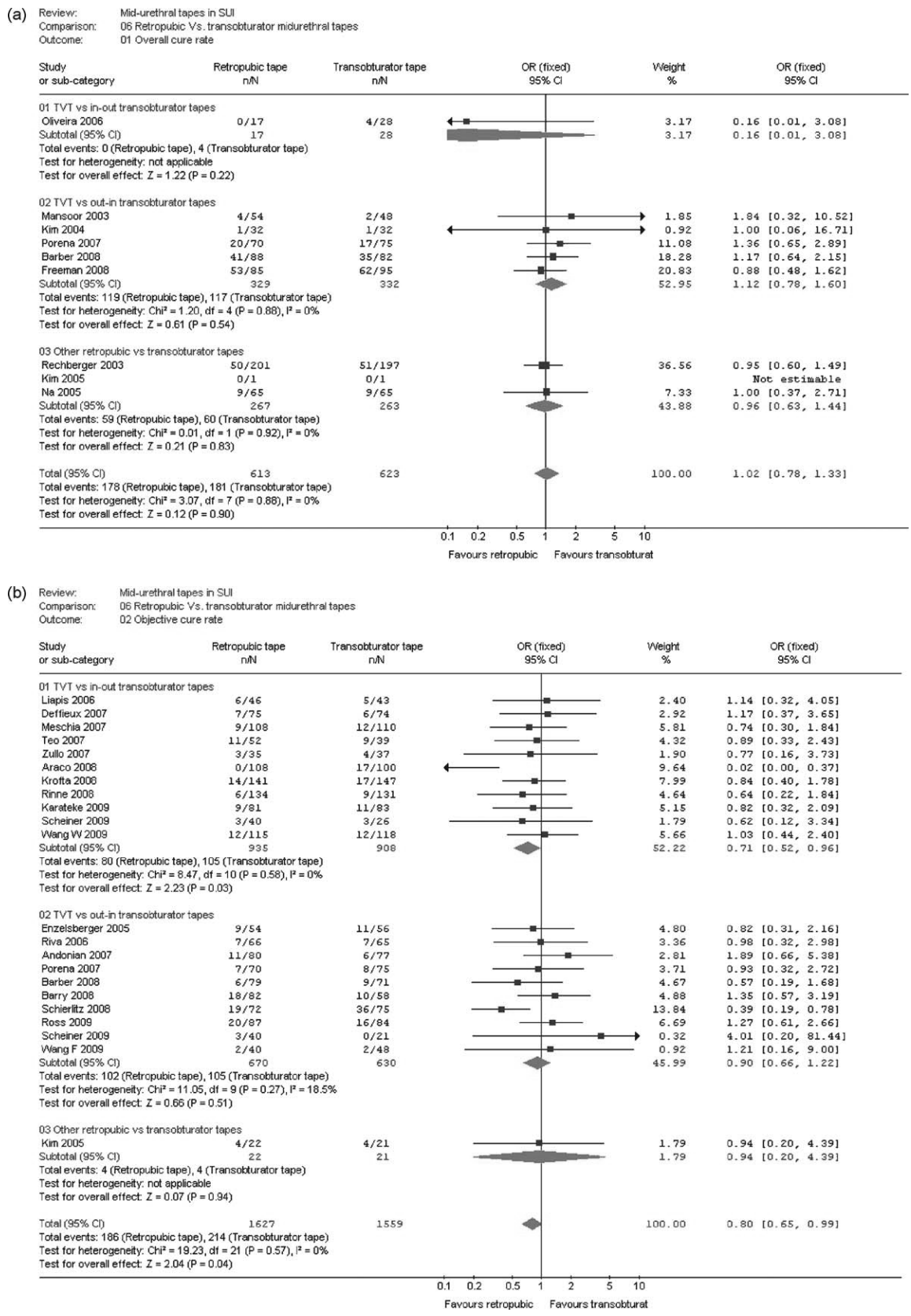


Fig. 4 – Forest plots of comparisons after retropubic tape (RT) and transobturator tape (TOT). (a) Continence rate according to any definition of cure; (b) objective continence rate; (c) subjective continence rate (nonvalidated questionnaire); (d) postoperative Urogenital Distress Inventory–6 score; (e) postoperative Incontinence Impact Questionnaire–7 score; (f) bladder or vaginal perforation; (g) hematoma; (h) vaginal erosion; (i) urinary tract infection; (j) storage lower urinary tract symptoms (LUTS); (k) voiding LUTS; (l) need of clean intermittent catheterization or recatheterization; (m) reoperation rate.

CI = confidence interval; CIC = clean intermittent catheterization; OR = odds ratio; SD = standard deviation; SUI = stress urinary incontinence.

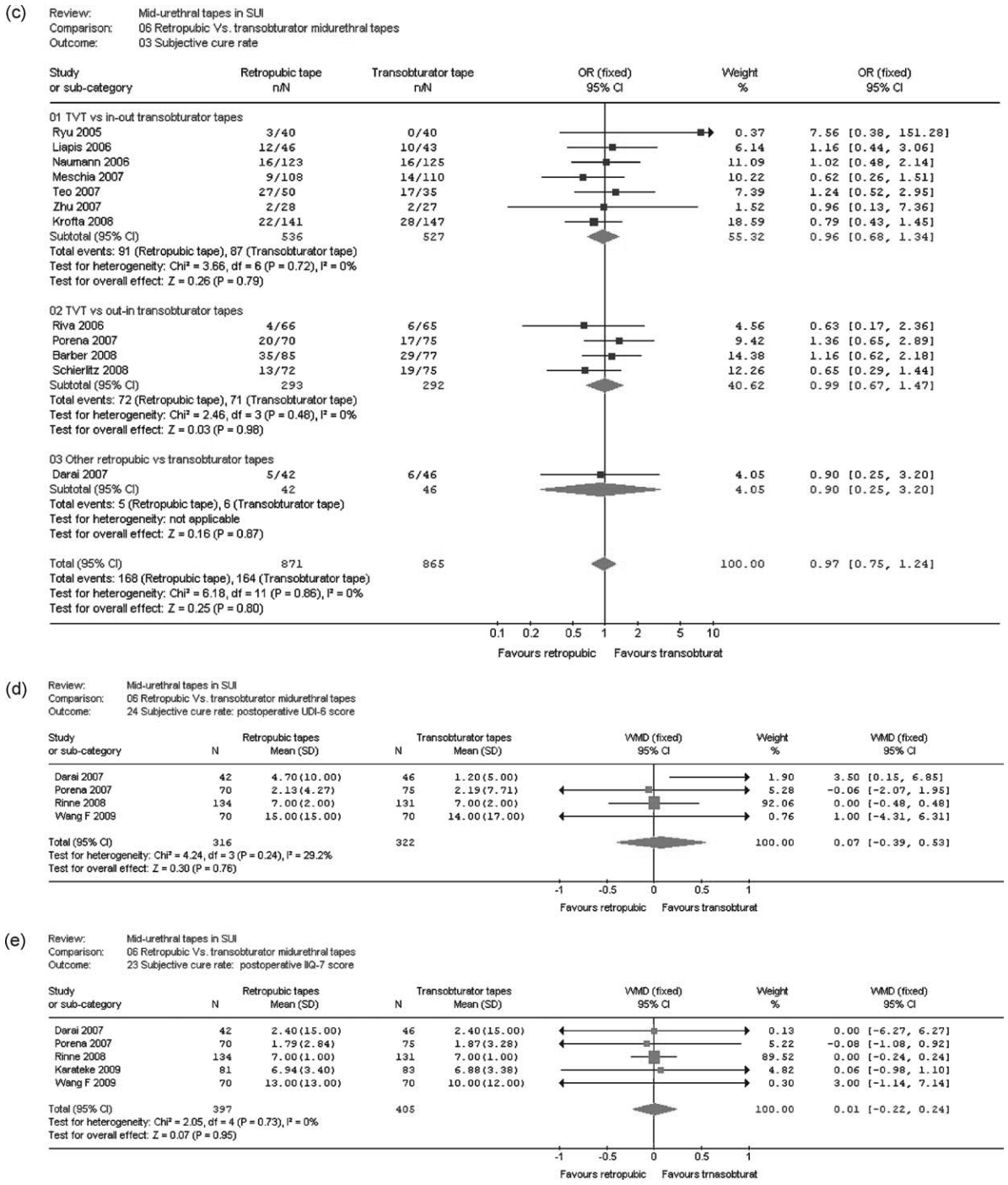
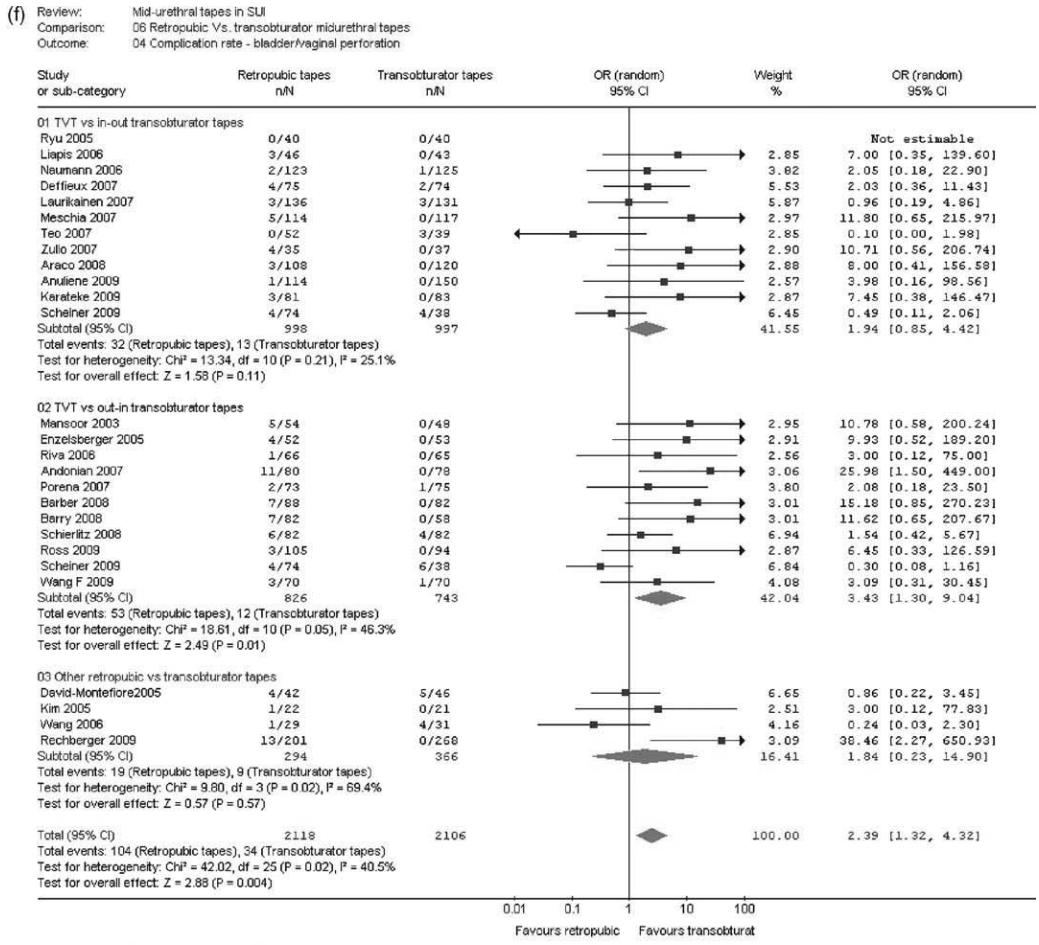


Fig. 4. (Continued)

With regard to complications, not surprisingly, bladder or vaginal perforations (OR: 2.5; 95% CI OR: 1.75–3.57; $p < 0.0001$; Fig. 4f) were significantly more common following RTs, without any significant difference between inside-out and outside-in TOT. Again, as expected, the prevalence of postoperative hematoma was significantly more common following placement of RT (OR: 2.62; 95% CI OR: 1.35–5.08; $p = 0.005$; Fig. 4g). In fact, the rates of vaginal erosion were slightly higher following TOT (OR: 0.64; 95% CI OR: 0.41–0.97; $p = 0.04$; Fig. 4h), due to the studies using Obtape, a device retired from the market due to a high risk of erosions. Finally, the risk of urinary tract infections (OR: 0.95; 95% CI OR: 0.69–1.31; $p = 0.74$; Fig. 4i), the need for clean intermittent catheterization or recatheterization (OR: 1.16; 95% CI OR: 0.84–1.59; $p = 0.37$; Fig. 4l), and the reoperation rate (OR: 1.1; 95% CI OR: 0.75–1.59; $p = 0.62$; Fig. 4m) were fairly similar between RT and TOT. Interestingly, the prevalence of storage LUTS was significantly higher in those patients randomized to RT (OR: 1.35; 95% CI OR: 1.05–1.72; $p = 0.02$; Fig. 4j), without any

(f)



(g)

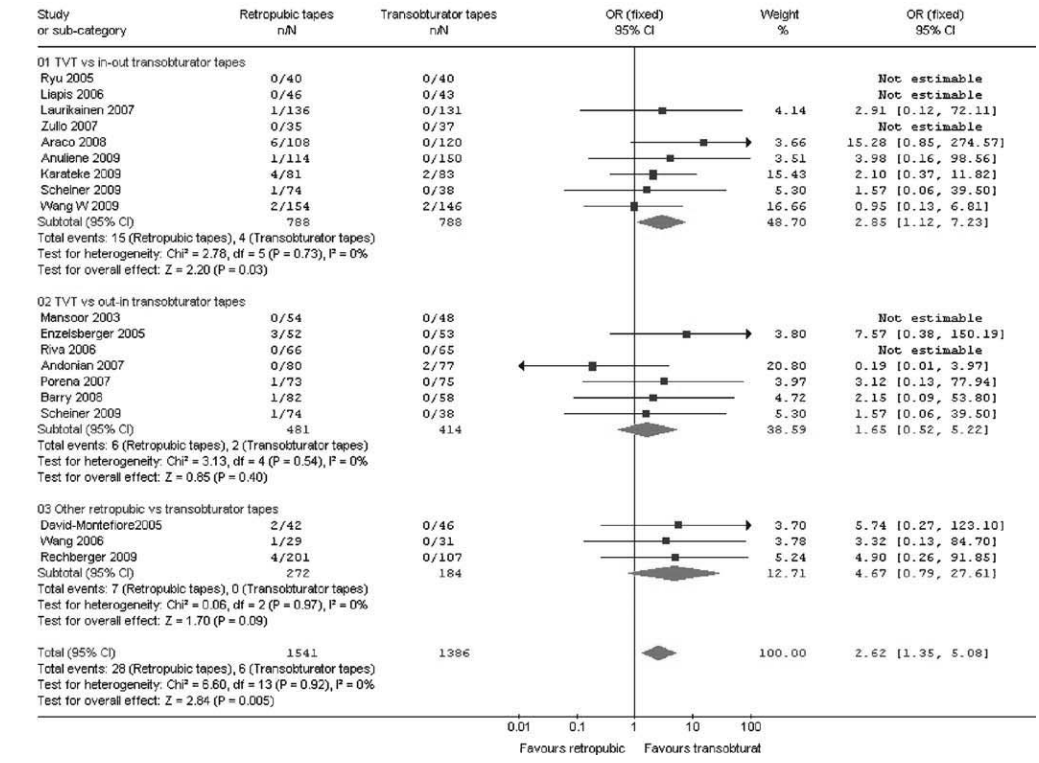
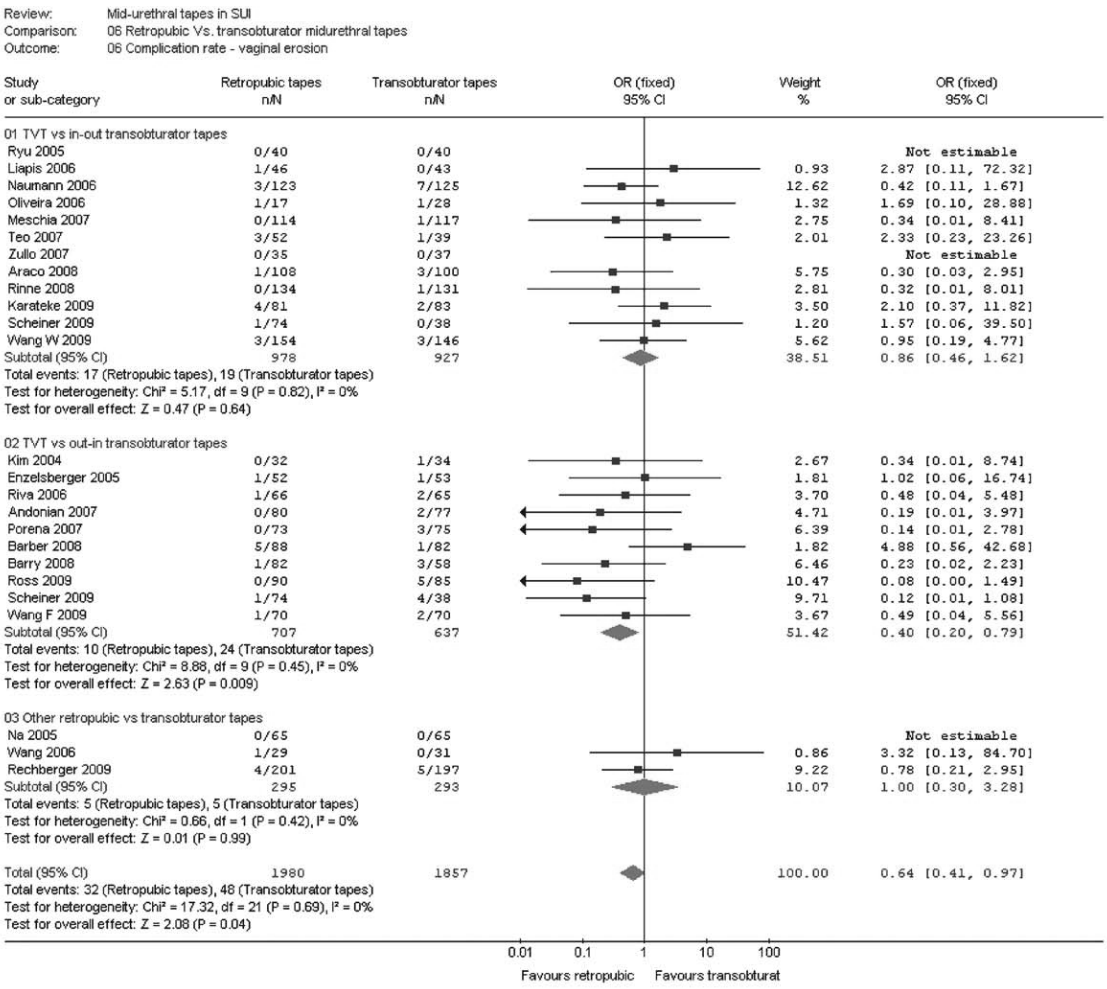


Fig. 4. (Continued)

(h)



(i)

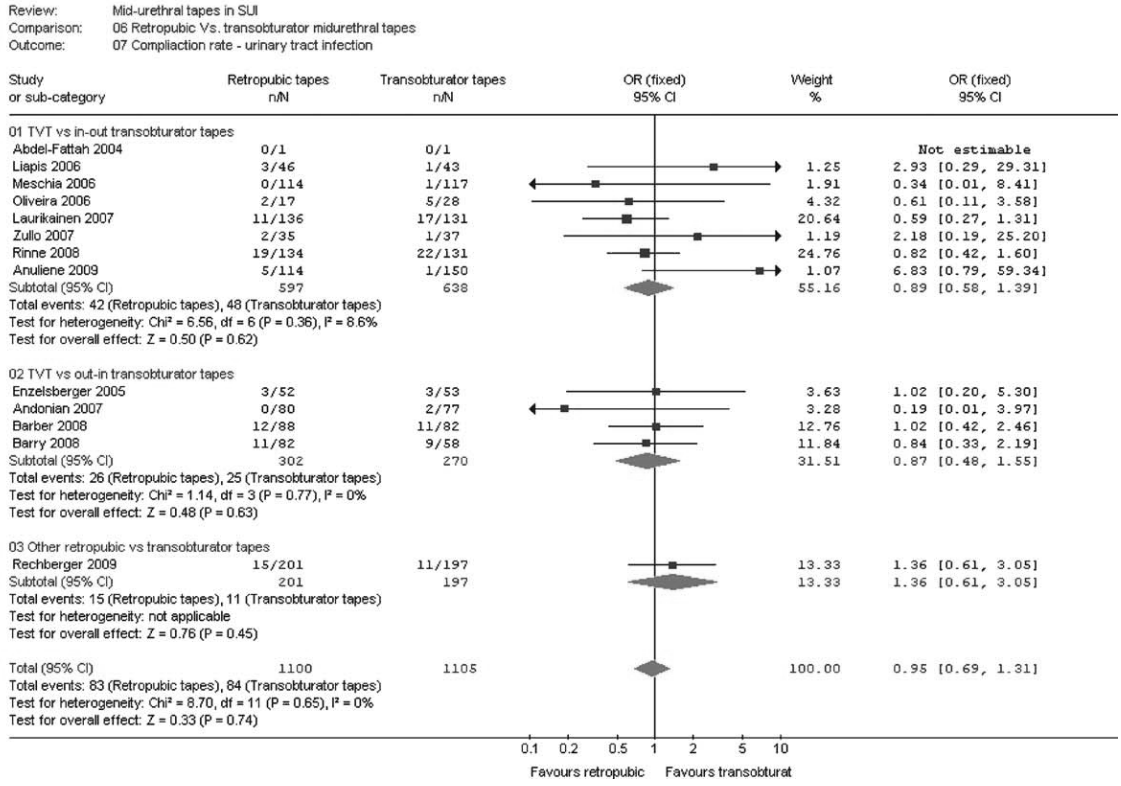
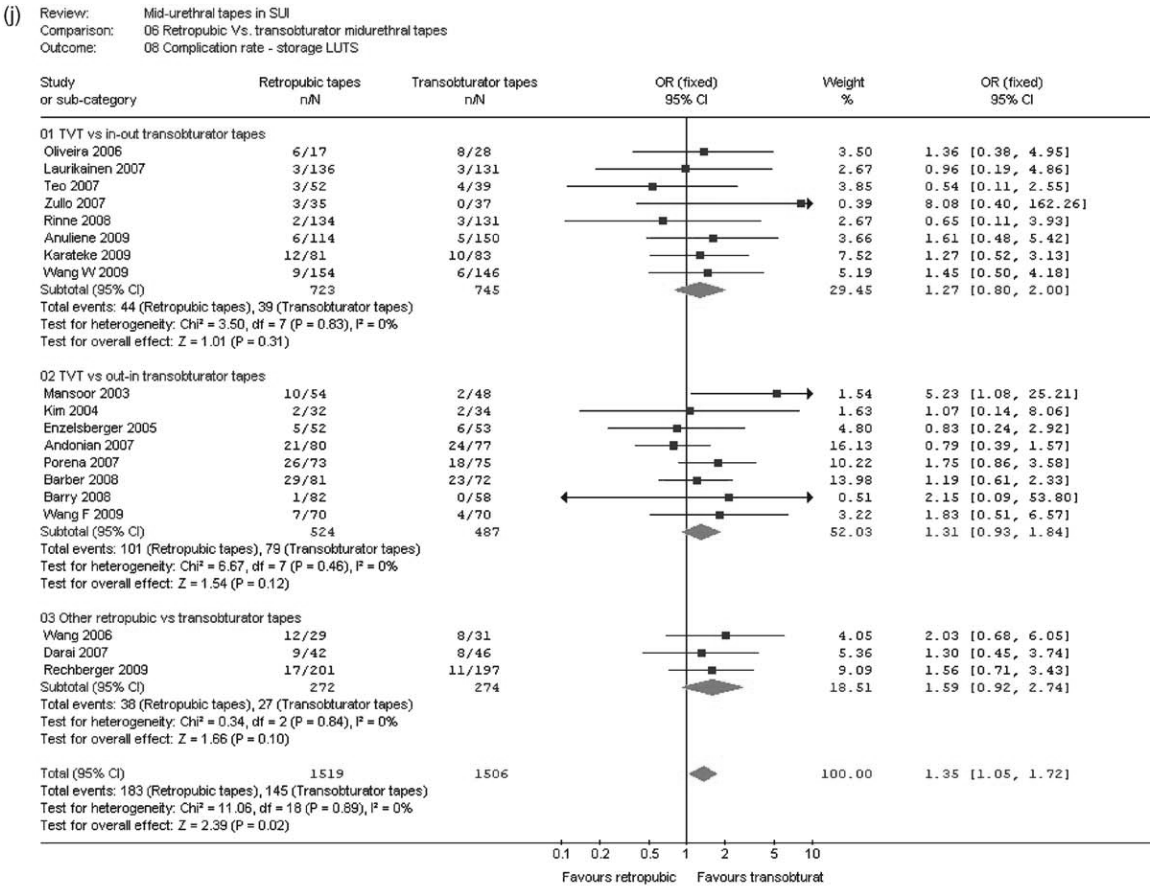
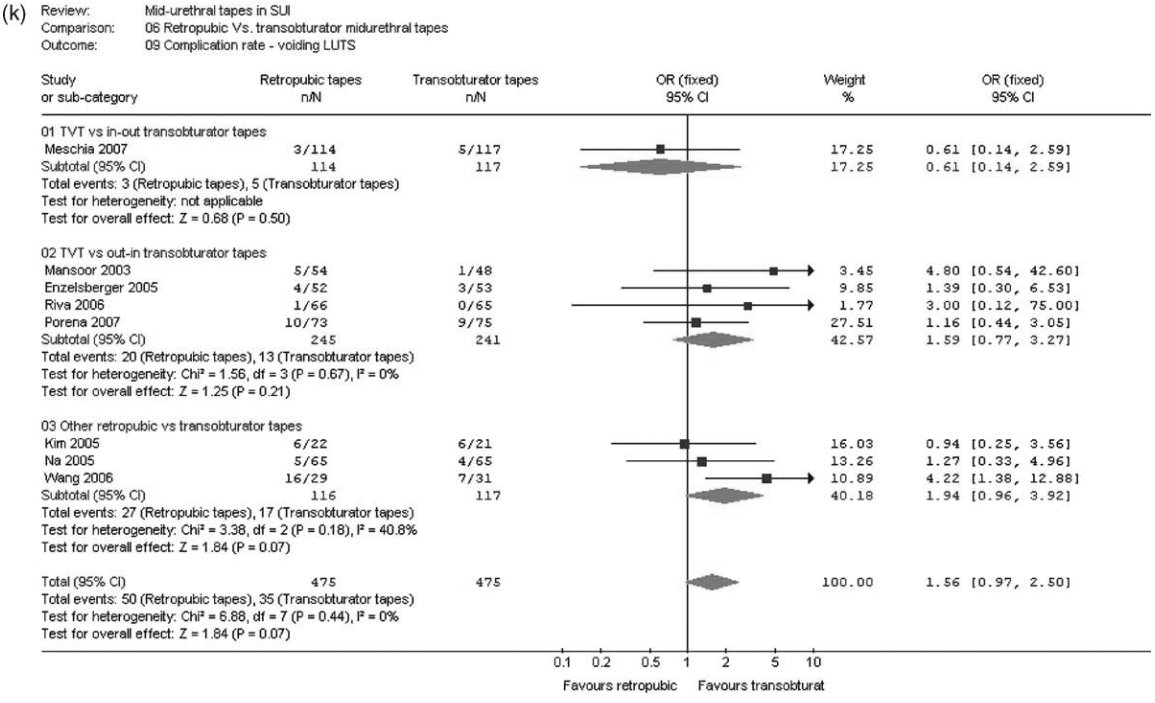


Fig. 4. (Continued)

(j)



(k)



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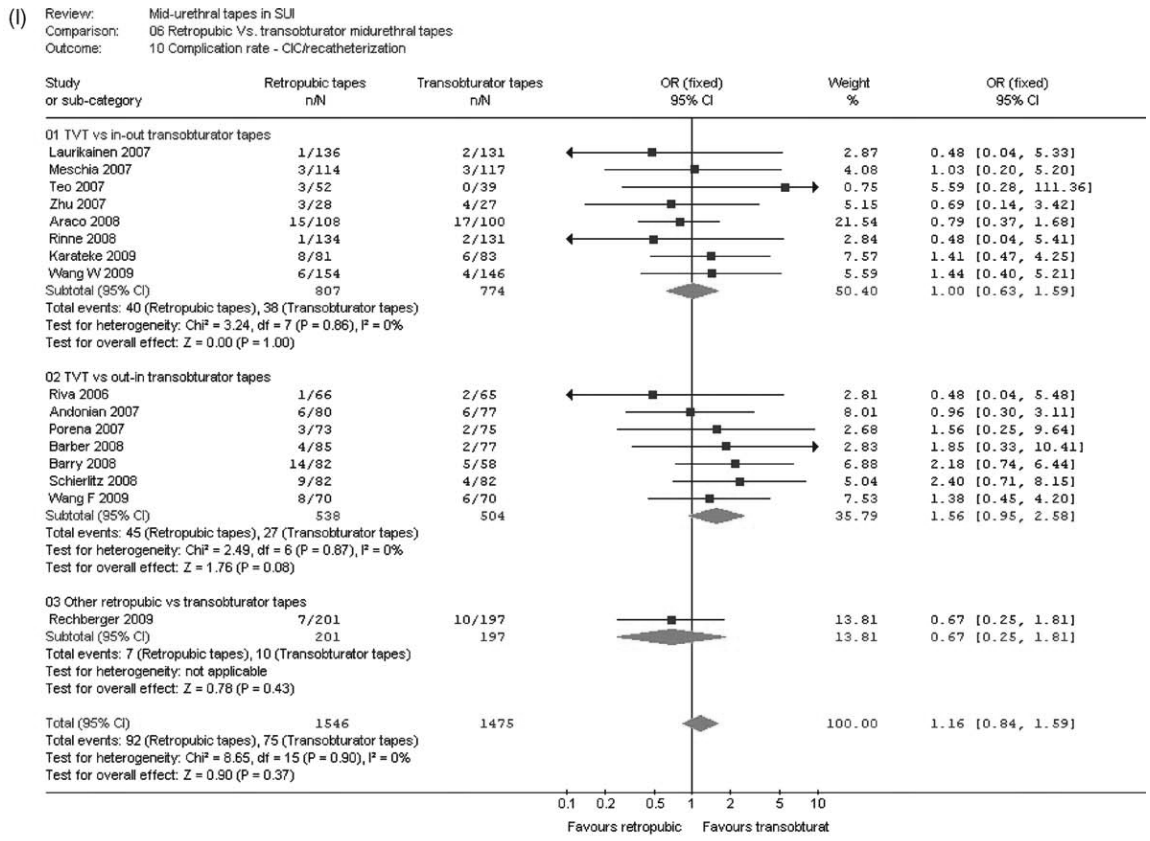

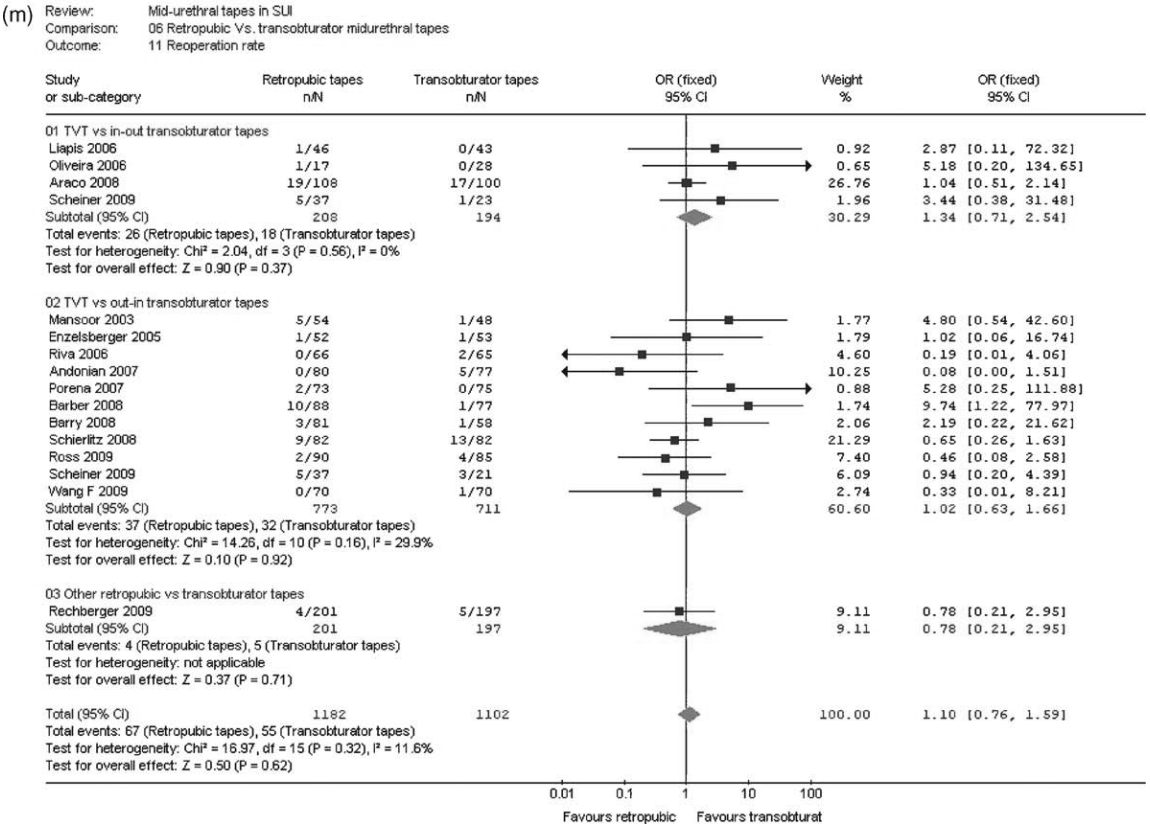

Fig. 4. (Continued).

Table 2 – Comparisons after retropubic tape and transobturator tape: Meta-analysis of all the randomized controlled trials (RCTs) and sensitivity analyses for high-quality RCTs

Retropubic vs transobturator tapes	All RCTs						High-quality RCTs					
						Continence rate						
	RCT	Participants	OR	95% CI of OR	*p* value	Difference in favor of	RCT	Participants	OR	95% CI of OR	*p* value	Difference in favor of
Any definition of continence	9	1236	1.02	0.78–1.33	0.90	None	2	315	1.24	0.78–1.99	0.36	None
Objective continence rate	22	3186	0.80	0.65–0.99	0.04	RT	9	1481	0.74	0.54–1.01	0.05	None
Subjective continence rate	12	1736	0.97	0.75–1.24	0.80	None	5	727	0.95	0.66–1.36	0.77	None
Postoperative UDI-6 score	4	638	0.07*	−0.39–0.53	0.76	None	2	410	0*	−0.47–0.47	0.99	None
Postoperative IIQ-7 score	5	802	0.01*	−0.22–0.24	0.95	None	3	574	0*	−0.23–0.23	0.99	None
						Adverse events						
	RCT	Participants	OR	95% CI of OR	*p* value	Difference in favor of	RCT	Participants	OR	95% CI of OR	*p* value	Difference in favor of
Bladder/vaginal perforation	27	4224	2.5	1.75–3.57	<0.0001	TOT	10	1624	2.52	1.41–4.52	0.002	TOT
Hematoma	19	2927	2.62	1.35–5.08	0.005	TOT	5	711	2.54	0.72–8.96	0.15	None
Vaginal erosion	25	3837	0.64	0.41–0.97	0.04	RT	8	1285	0.79	0.37–1.68	0.54	None
Urinary tract infection	13	2205	0.95	0.69–1.31	0.74	None	4	774	0.81	0.53–1.25	0.34	None
Storage LUTS	19	3025	1.35	1.05–1.72	0.02	TOT	7	1129	1.44	0.99–2.09	0.06	None
Voiding LUTS	8	950	1.56	0.97–2.5	0.07	None	3	439	1.59	0.85–2.97	0.15	None
CIC/recatheterization	16	3021	1.16	0.84–1.59	0.37	None	8	1456	1.29	0.75–2.22	0.35	None
Reoperation rate	16	2284	1.1	0.75–1.59	0.62	None	4	652	1.24	0.66–2.35	0.5	None

CI = confidence interval; CIC = clean intermittent catherization; IIQ = Incontinence Impact Questionnaire; LUTS = lower urinary tract symptoms; OR = odds ratio; RT = retropubic tape; TOT = transobturator tape; UDI = Urogenital Distress Inventory.
* Weight mean difference.

significant difference between inside-out and outside-in TOT. A nonstatistically significant difference in favor of TOT was found for voiding LUTS (OR: 1.56; 95% CI OR: 0.97–2.5; $p = 0.07$; Fig. 4k). In sensitivity analyses limited to studies of higher methodological quality, only a nonstatistically significant trend in favor of TOT was found for storage LUTS (OR: 1.44; 95% CI OR: 0.99–2.09; $p = 0.06$) and voiding LUTS (OR: 1.59; 95% CI OR: 0.85–2.97; $p = 0.15$). Similarly, with regard to the risk of all the other complications and reoperation, no differences were identified in the other sensitivity analyses (Table 2).

3.4. *Randomized controlled trials comparing different transobturator midurethral tapes*

But and Fagenelj randomized 120 patients to TVT-O or Monarc, demonstrating similar objective and subjective continence rates at 4-mo follow-up [58]. However, a significantly higher number of vaginal perforations occurred in the patients randomized to Monarc (0% vs 15%), and the inside-out procedure was significantly more painful than the outside-in one in the first 6 h after surgery. Similarly, Liapis et al evaluated 114 patients randomized to TVT-O ($n = 61$) or Monarc ($n = 53$), reporting fairly similar 12-mo continence and complication rates [59]. Similar data were reported by Houwert et al in a congress abstract [57]. Only the study by But and Fagenelj [58] was of good methodological quality.

Supplemental Table 5 in the appendix summarizes continence, complication, and reoperation rates of the RCTs, comparing different TOT as the treatment for primary SUI.

Fig. 5 shows the forest plots concerning the meta-analyses of objective continence and the rates of urinary tract infections (UTIs).

Both objective continence rate (OR: 1.96; 95% CI OR: 0.84–4.53; $p = 0.12$; Fig. 5a) and UTIs (OR: 1.91; 95% CI OR: 0.73–5.01; $p = 0.19$; Fig. 5b) were similar in the two procedures.

3.5. *Publication bias*

Funnel plots of all the studies used in this meta-analysis were generated for all the evaluated comparisons. Only eight studies [41,49,54,61–65] lay outside the 95% CI with an even distribution about the vertical, suggesting little evidence of publication bias (see Supplemental Figs. 1–4 in the appendix).

3.6. *Discussion*

Open retropubic colposuspension, autologous fascial slings, and midurethral tape are recommended for the management of primary SUI, according to the recent recommendations of the 4th International Consultation on Incontinence [66]. Significant changes in clinical practice have been observed over the past decade, with the number of colposuspensions and autologous slings declining considerably, mainly in favor of TVT [67].

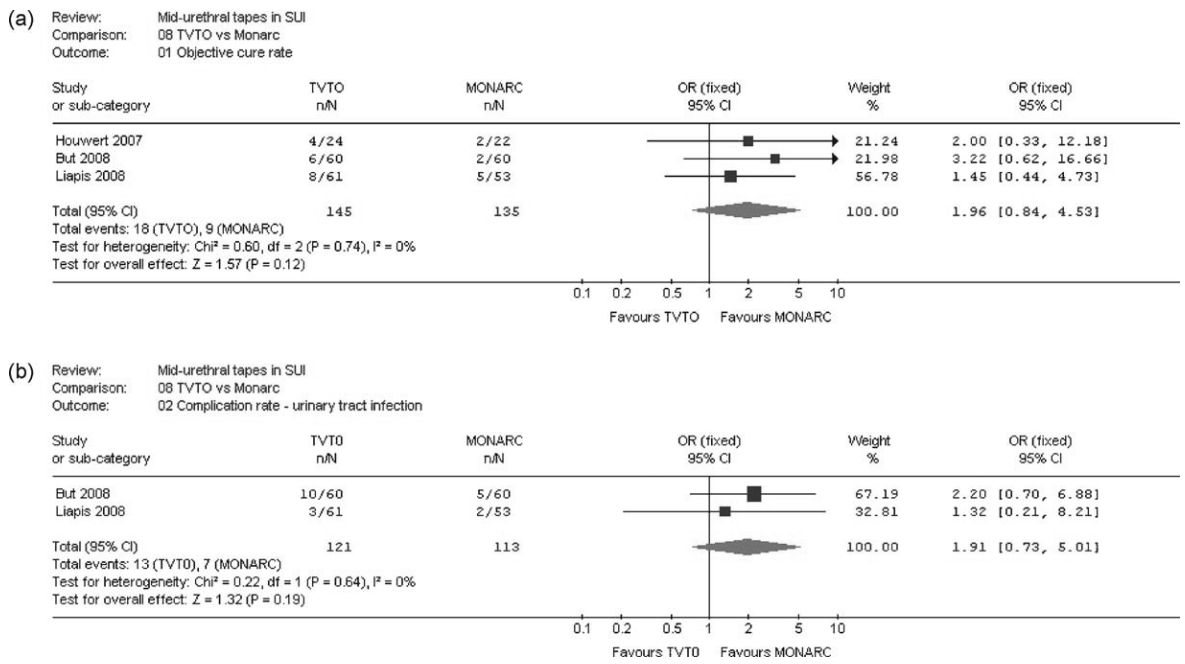

Fig. 5 – Forest plots of comparisons after different transobturator tapes (TOTs). (a) Objective continence rate; (b) urinary tract infection. CI = confidence interval; OR = odds ratio; SUI = stress urinary incontinence.

These changes in practice, however, seem to be proceeding in advance of high-quality evidence, or at least based only on short- and midterm follow-up evidence. Because of the large number of RCTs available, many with conflicting results, and because of the demand for evidence-based medicine, several meta-analyses of RCTs have been reported [11,12,16,68–71], with only three focused on the comparison of midurethral tapes with other surgical treatments [11,12,16]. Following the publication of several other RCTs and follow-up extensions on some of the previously available studies, we elected to update our two previous meta-analyses. We found that midurethral tapes were followed by significantly higher overall and objective continence rates than Burch colposuspension, although bladder perforations were more common after RT. Although midurethral and pubovaginal slings were reconfirmed to be similarly effective in the treatment of SUI, pubovaginal slings were found to be more frequently associated with storage LUTS, although intraoperative bladder perforations were less common with pubovaginal slings. Notably, classic TVT was shown to be followed by significantly higher objective continence rates than TOT, but the data were not reconfirmed in sensitivity analyses limited to high-quality trials; however no difference was noted in subjective continence rates. What is evident is that such benefits are basically at the cost of higher risks of intraoperative complications such as bladder or vaginal perforations and postoperative hematoma. Furthermore, storage LUTS was also slightly more common after RT. No new RTCs comparing different RT have been published since 2007. With regard to TOT, the available data from two RCTs failed to show any significant difference between two TOT (ie, TVT-O and Monarc). Finally, no RCT evaluating readjustable slings or single-incision tapes were available.

On the whole, the figures of the meta-analysis seem to support the increasing role of midurethral tapes and, specifically, of TOT in the setting of the primary treatment of the patients with SUI. However, those data raise several concerns regarding outcome measures, reporting of complications, and follow-up. Overall, the present meta-analysis included a significant number of RCTs with good methodological quality as judged by the Jadad score, and it generated consistent results in all the sensitivity analyses. However, even considering the lack of statistical power in most studies overcome by the meta-analysis strategy, and assuming uniformity of surgical techniques in the different RCTs, the variations in the outcome measures used, the length of follow-up, and the handling of cases lost to follow-up still remain significant concerns. In particular, when considering outcome measures, the definitions of cure used can affect the study results significantly. For example, evaluating data from the UK TVT trial, Hilton demonstrated success rates lower than 30% for both TVT and Burch colposuspension applying both subjective and objective continence rates, whereas >60% of the same patients could be considered cured based on the absence of urodynamic SUI or on a negative pad test [72]. Similarly, Albo et al, reporting the data of the Stress Incontinence Surgical Treatment Efficacy Trial, demonstrated that about 15% of the patients in each arm have to be considered as surgical failures based on the presence of a positive pad test. However, using more stringent criteria such as the concomitant presence of no self-reported symptoms of SUI, no SUI episodes recorded in a 3-d diary, a negative

urinary stress test, and no retreatment for SUI, about 40% of the patients randomized to pubovaginal sling and 60% of those having Burch colposuspension were surgical failures [73]. Consequently, standardized criteria to report patients' outcomes are desirable.

With regard to the tools used to assess outcomes, we found that only 21 RCTs of 76 used validated questionnaires to evaluate subjective cure rates, the impact of SUI on quality of life, and the association of SUI and SUI treatments with LUTS and sexual function. In fact, a multitude of different tools were applied (Bristol Female Lower Urinary Tract Symptoms questionnaire, EQ-5D, King's College Health Questionnaire, Incontinence Severity Index, International Consultation on Incontinence-Short Form, Incontinence Impact Questionnaire score, Incontinence Quality of Life score, Patient's Global Expression of Severity, Medical Outcomes Study 12-Item, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, Short Form Urinary Distress Inventory, Women Irritative Prostate Symptoms Score), making comparisons very hard. A standardized assessment, perhaps applying the International Consultation on Incontinence modular questionnaire, is highly recommended.

With regard to complications, a very limited number of major complications was observed in the evaluated RCTs, although bowel, vascular, and nerve injuries, necrotizing fasciitis, ischiorectal abscess, urethrovaginal fistulas, sepsis, and patient deaths have been reported after placement of RT and TOT. Specifically, Deng et al reported on the prevalence of major complications in the US Food and Drug Administration's Manufacturer and User Facility Device Experience database, identifying 32 cases of vascular injuries, 33 bowel injuries, and 8 patient deaths after TVT placement [74]. Due to the low prevalence of such complications, surgical series and, above all, national or manufacturer registries should be considered more reliable, and their implementation should be strongly recommended. Moreover, most of the complications reported in the available RCTs were intraoperative ones, with a limited number of studies providing data on the intermediate- and long-term functional sequelae. That is of outmost importance because some underreported complications, including storage and voiding LUTS, can be disabling for the affected patients, whereas some intraoperative complications such as bladder injury during placement of RT are of little or no implication provided they are promptly recognized and treated.

With regard to follow-up duration, only two studies reported data at follow-up of $\geq$60 mo [26,27], which clearly does not allow either the durability of efficacy or the presence of long-term morbidity and functional complications to be adequately evaluated. That is clearly a major deficit in our knowledge base. Moreover, in most studies, patients lost to follow-up were simply deleted from the analyses, and their outcomes were assumed to be similar to those of the whole cohort. This approach has to be regarded as incorrect, and assumptions should be made on their outcomes (eg, considering all study dropouts as cured or as failures, or carrying forward the last postoperative data), in order to provide more realistic estimations of the results [27].

4. Conclusions

The literature summarized in this meta-analysis showed RT to be significantly more effective than colposuspension but to have a higher risk of intraoperative bladder perforation. Pubovaginal slings and midurethral tapes were shown to be similarly effective in the treatment of SUI, with storage LUTS more prevalent following pubovaginal slings, and intraoperative bladder perforation more common with RT. Classic TVT appeared to be followed by significantly higher objective continence rates than TOT but with no difference in subjective continence rates and at the cost of higher risks of intraoperative complications and storage LUTS. Finally, no significant differences were identified in the studies comparing different TOT head to head. Statistically speaking, many trials were of good methodological quality, and sensitivity analyses limited to only high-quality studies reconfirmed most of the previously mentioned findings. From a clinical point of view, the heterogeneity in outcome measures and the lack of RCTs with long-term follow-up represent significant deficits in the evidence base and limit our ability to counsel patients about longer term outcomes. Standardization of outcome measures used, handling of data with regard to patients lost to follow-up, and consensus on what type of cure we are discussing in trials with a follow-up of $\geq$5 yr are clearly needed.

Author contributions: Giacomo Novara had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Novara, Ficarra, Artibani
Acquisition of data: Novara, Ficarra.
Analysis and interpretation of data: Novara, Ficarra, Artibani.
Drafting of the manuscript: Novara.
Critical revision of the manuscript for important intellectual content: Barber, Chapple, Constantini, Hilton, Nilsson, Waltregny.
Statistical analysis: Novara.
Obtaining funding: None.
Administrative, technical, or material support: None.
Supervision: None.
Other (specify): None.

Financial disclosures: I certify that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: Giacomo Novara and Walter Artibani have no current financial interests to declare; they were both previously investigators in a randomized control trial (RCT) of surgery for stress urinary incontinence (SUI) funded by Gynecare (2005–2006). Paul Hilton has no current financial interests to declare; he was previously the lead investigator in a RCT of surgery for SUI funded by Gynecare (1998–2003) and received research funding from Gynae Ideas for development work into devices for the treatment of SUI and pelvic organ prolapse (2001–2003); he has also received reimbursement of travel expenses to attend meetings in relation to these studies. He was the guideline development group lead for the National Institute for Health and Clinical Excellence clinical guideline on urinary incontinence in women (2004–2007), a member of the "Surgery for Incontinence in Women" group within the 4th International Consultation on Incontinence

(2007–2009), and currently is a member of the Clinical Evaluations and Trials Prioritisation Group of the National Institute for Health Research Health Technologies Assessment programme (2008–present). David Waltregny is a consultant for Ethicon. The University of Liège owns the TVT-Obturator patent.

Funding/Support and role of the sponsor: None.

Appendix A. Supplementary data

Supplemental tables and figures accompanying this article can be found in the online version at doi:10.1016/j.eururo.2010.04.022 and via www.europeanurology.com.

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